DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

April 9, 2002

Larry and Pat Frieders
Pharmacist
The Compounding Pharmacy
575 W. Illinois Ave.
Aurora, IL 60506

Larry and Pat Frieders
Pharmacist
Techni-Med, Inc.
575 W. Illinois Ave.
Aurora, IL 60506

Dear Mr. and Ms. Frieders:

This letter concerns **Nicotine Lollipops and Nicotine Lip Balm** which are currently marketed by your firm as shown on your Internet site www.thecompounder.com. According to information on this site, **Nicotine Lollipops** consist of Nicotine Salicylate combined with a natural sweetener, and flavorings in a sugar-free base, and is available in a 2 mg. dosage. According to information on this site, **Nicotine Lip Balm** consists of nicotine salicylate in a flavored, sweetened (no sugar added) vehicle. Based on the descriptions of these products on your Internet site, the **Nicotine Lollipops** and **Nicotine Lip Balm** are intended as an aid for smoking cessation or to reduce nicotine addiction.

The intended uses noted above are conveyed through claims for **Nicotine Lollipops** on your Internet site. These include statements such as "...What is the Nicotine Lollipop? It is Nicotine Salicylate ...For most people who smoke a pack of cigarettes per day the 2mg strength is perfect...How do I use the Nicotine Lollipop? Place the lollipop in your mouth when you feel the urge to smoke...Leave it there until the urge passes and then replace the lollipop into the bag...Re-use the same lollipop next time the urge strikes...One lollipop usually last 4 to 5 cigarette breaks. How can nicotine replacement help me quit smoking? They help smokers quit by suppressing the symptoms of nicotine withdrawal.... The Nicotine lollipop can greatly assist those people who really want to quit smoking... The lollipop allows the individual to control the amount of nicotine taken based on the body's need at the time. A significant element of cigarette smoking is psychological and Nicotine lollipops deal with both the hand-to-mouth fixation and the physical dependence on nicotine..."

The intended uses noted above for **Nicotine Lip Balm** are conveyed through claims on your Internet site. These include statements such as "...Nicotine Lip Balm...looks like chapstick...Licking your lips can help you Lick The Habit...Applying the balm to your lips leaves a thin film that contains 0.2 to 0.4mg of nicotine (each tube provides 75 to 150 doses of nicotine). It is absorbed into your body through your lips and when you lick them. This product is for use by people who smoke regularly...help relieve the craving for nicotine...designed to help a person quit...discreetly apply the lip balm to your lips and the nicotine craving will subside..."

Based on the intended uses established by your Internet site, your **Nicotine Lollipops,** 2 mg. and **Nicotine Lip Balm,** 0.2 mg., and 0.4 mg., are "drugs" as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The **Nicotine Lollipops,** 2 mg., and **Nicotine Lip Balm,** 0.2 mg., and 0.4 mg., do not qualify for the exemptions from sections 505 and 502(f)(1) provided under section 503A of the Act since, according to your Internet site, you do not appear to require prescriptions to be presented to compound the products. Among other requirements, to qualify for the statutory exemption provided by Section 503A, drugs must be compounded based on the receipt of valid prescription orders from licensed practitioners. You must also use only those bulk drug substances that conform to Section 503A(b)(1)(A). Nicotine salicylate, which is reportedly used in all of your **Nicotine Lollipops and Nicotine Lip Balm** products, is not a component of an FDA approved drug, is not listed in a United States Pharmacopoeia (USP) or National Formulary (NF) monograph, and was not nominated for inclusion in a list of bulk drug substances for compounding. Although nicotine and nicotine polacrilex are components of FDA approved drugs and are listed in the USP/NF, nicotine salicylate is not. Therefore, nicotine salicylate is not permitted for use in compounding.

Your **Nicotine Lollipops,** 2 mg., and **Nicotine Lip Balm,** 0.2 mg., and 0.4 mg., are also subject to Title 21 of the Code of Federal Regulations (CFR) section 310.544. Under that regulation, they are "new drugs" as defined by section 201(p) of the Act. Under Section 505(a) of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. We note that your **Nicotine Lollipops,** 2 mg., and **Nicotine Lip Balm,** 0.2 mg., and 0.4 mg., drug products are not the subject of FDA-approved NDAs and, therefore, they may not be marketed in the United States. The continued distribution of these products without approved NDAs violates Section 505 of the Act.

Nicotine Lollipops, 2 mg., and **Nicotine Lip Balm,** 0.2 mg., and 0.4 mg., are misbranded within the meaning of section 502(o) of the Act in that they are manufactured in an establishment not duly registered under section 510 of the Act and they have not been listed as required by section 510(j) of the Act. In addition, **Nicotine Lollipops,** 2 mg., and **Nicotine Lip Balm,** 0.2 mg., and 0.4 mg., may be misbranded under section 502(f)(1) of the Act on the grounds that their labeling fails to bear adequate directions for the uses for which they are being offered and they would not be exempt from this requirement under 21 CFR section 201.115 since they are unapproved new drugs. These

products may also be misbranded under Section 502(f)(2) of the Act on the grounds that their labeling fails to bear such adequate warnings against use by children where their use may be dangerous to health.

This letter is not intended to be an all-inclusive review of your Internet sites and the products your firm may market. The violations of the Act described above are not intended to be an all-inclusive list of the deficiencies of you and your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with Federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We request that you reply in writing within fifteen (15) days of your receipt of this letter stating the action your firm will take to discontinue marketing of these drug products. Your response should be directed to Melvin F. Szymanski, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance. Metropark North I, Room 200, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

David J. Horowitz, Esq.
Acting Director,
Office of Compliance
Center for Drug Evaluation and Research

cc: [ ]